IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: :
EDWARD L. TOBINICK

     665525   :

Serial No.: 09/476,643   Group Art Unit 1614

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Filed: December 31, 1999   Examiner William R. A. Jarvis

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For: TNF INHIBITORS FOR THE   September 5, 2000
      TREATMENT OF NEUROLOGICAL , :
      RETINAL AND MUSCULAR
      DISORDERS   :

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION TO MAKE SPECIAL
(MPEP Section 708.02)

Sir:

Applicant hereby files this Petition to make special this application for purposes of

examination and payment of the issue fee, on the grounds of a pre-examination search.

Applicant also submits the petition fee.

    The application presents claims directed to a single invention of treating neurological

disorders. In case the Examiner believes that there is more than one invention, applicant

hereby elects without traverse Claims 30 to 49, and 98 and 99.

SEARCH AREAS

A pre-examination search was made of the records of the U.S. Patent Office by applicant's attorney, Ezra Sutton. The field of search included Class 424, Subclasses 85.1, 133.1, 134.1, 143.1, 144.1, 145.1, and 158.1; Class 435, Subclasses 69.1, 69.7, 172.3, and 240.27; and Class 530, Subclasses 350, 351, 387.1, 387.3, 388.2, 388.23, 388.4, 866, and 868. Also, a computer search was performed using the terms TNF and tumor necrosis factor.

INVENTION SEARCHED

The inventions searched are tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

PATENTS SELECTED IN SEARCH

U.S. Patent No.	Inventor	Issue Date
5,574,022	ROBERTS et al	11/12/1996
5,605,690	JACOBS et al	02/25/1997

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5,650,396	CARLINO et al	07/22/1997
5,656,272	LE et al	08/12/1997
5,756,482	ROBERTS et al	05/26/1998

A copy of each patent is enclosed.

DISCUSSION OF PATENTS

U.S. Patent Nos. 5,756,482 and 5,574,022 to ROBERTS et al disclose methods of attenuating physical damage to the nervous system and to the spinal cord after injury using steroid hormones or steroid precursors such as pregnenolone and pregnenolone sulfate in conjunction with a non-steroidal, anti-inflammatory substance such as indomethacin. These prior art patents do not teach the use of TNF antagonists or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat "Neurologic and Related TNF Disorders", as in the present invention.

U.S. Patent No. 5,605,690 to JACOBS et al discloses a method for treating TNF-dependent inflammatory diseases such as arthritis by administering a TNF antagonist, such as soluble human TNFR (a sequence of amino acids), to a human. This prior art patent does not teach the use of TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat "Neurologic and Related TNF Disorders", as in the present invention.

U.S. Patent No. 5,656,272 to LE et al discloses methods of treating TNF-alpha-mediated Crohn's disease using chimeric anti-TNF antibodies. This prior art patent does not

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teach the use of TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat "Neurologic and Related TNF Disorders", as in the present invention.

U.S. Patent No. 5,650,396 to CARLINO et al discloses a method of treating multiple sclerosis (MS) by blocking and inhibiting the action of TNF in a patient. This prior art patent does not teach the use of TNF antagonists, as in the present invention.
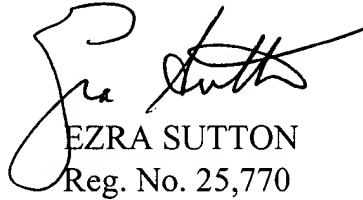
CONCLUSION

None of the prior art patents disclose or teach the use of the TNF antagonists or TNF blockers of the present invention for the suppression and inhibition of the action of TNF in a human to treat "Neurologic and Related TNF Disorders", in which the TNF antagonist gives the patient a better opportunity to heal, slows disease progression, prevents neurological damage, or otherwise improves the patient's health.

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These prior art patents <u>do not</u> disclose or teach the specific subject matter recited in Claims 30 to 49, and 98 and 99. Accordingly, these claims are patentable and this Petition should be granted.

Respectfully submitted,

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Enclosures